

## REMARKS

### Sequence Compliance

Applicants amended the specification to insert sequence identifiers consistent with the paper copy and computer readable form of a sequence listing previously submitted in the instant application on February 28, 2002.

### Claim Objections

In the action, the examiner rejected claims 1-3 for referring to "Gal-Gal" in the claims instead of its proper name. As such, applicants amended claim 1 to recite  $\alpha$ -D-Galp-(1-4)- $\beta$ -D-Galp.

### 35. U.S.C. § 112, 1<sup>st</sup> paragraph

The examiner rejected claim 3 allegedly for non-enablement, asserting that "the specification, while being enabling for a vaccine using pili from Gal-Gal binding pilus-producing *E.coli* bacteria for preventing pyelonephritis, does not reasonably provide enablement for a vaccine for preventing any or all urinary tract or other microbial infections or diseases." Office action at 4. In the interest of expediting prosecution, and without acquiescence to the examiner's rejection, applicants amended claims 1 and 3 to recite that the pilus-producing bacteria is an *E.coli* bacterium and that the vaccine is used for preventing pyelonephritis.

Similarly, applicants added new claim 8, which is drawn to a vaccine for preventing cystitis. Support for new claim 8 can be found on pages 9, line 1 to page 10, line 38 of the instant specification. This example describes *in vivo* studies in a BALB/c animal model for cystitis and discloses amino acid sequences protective for cystitis.

### 35 U.S.C. § 112, 2<sup>nd</sup> paragraph

The examiner rejected claims 1-3 for alleged indefiniteness, asserting that "immunodominant region" lacks antecedent basis and that "if a corresponding protective epitope..." is unclear. In the interest of expediting prosecution, applicants amended claims 1-3. Applicants trust that these amendments obviate the instant rejection.

### 35 U.S.C. § 103

Finally, the examiner rejected claims 1-3 as allegedly obvious over Pecha *et al.* (*J. Clin. Invest.*, 83:2102-08 (1989)), in view of Steidler *et al.* (*J. Bacteriol.*, 175:7639-43 (1993)) and further in view of Baga *et al.* (*Cell*, 49:241-51 (1987)). In particular, the examiner asserted that it would have been obvious “to modify the vector system of Steidler *et al.* by substituting the immunoglobulin G-binding domain of protein A of *Staphylococcus aureus* with the protective pili from a Gal-Gal binding pilus-producing bacteria of Pecha *et al.* to be inserted into *papA* as taught by Steidler *et al.* and further modifying the vector system...by mutating the *papH* gene...as taught by Baga.” Office action at 11.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references (or references when combined) must teach or suggest all the claim limitations. See MPEP 2142. Applicants respectfully assert that the presently claimed invention is not obvious over the prior art.

Steidler teaches insertion of a BamH1 fragment either after codon 7 or codon 68 of the *papA* gene. In addition, Steidler teaches that “a stretch of at least 58 amino acids can be inserted into PapA.” Steidler at 7643. Indeed, the IgG binding protein from *S.aureus* as described in Steidler is 58 amino acids long. This is in contrast with the present invention, which describes peptides up to 20 amino acids in length, wherein the corresponding nucleotide sequence is inserted into the *papa* gene that corresponds to the immunodominant region of PapA.

In the interest of expediting prosecution, applicants amended claim 1 to recite that the peptide is smaller than or equal to 20 amino acids in length. As such, Pecha, in view of Steidler and Baga do not teach each and every element of the claimed invention.

## CONCLUSION

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and arguments.

It is respectfully urged that the present application is now in condition for allowance. Early notice to that effect is earnestly solicited.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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